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ASSESSMENT FOR THE INTRODUCTION OF ZINC IN THE TREATMENT OF DIARRHEA IN MADAGASCAR

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The author's views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

Abstract

This report provides findings from an assessment, conducted from September 27 to October 7, 2005, to identify requirements for the successful introduction of zinc to treat diarrhea in Madagascar.

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Acronyms

ADRA	Adventist Development And Relief Agency
ASOS	Action Santé Organisation Secours (Action Health and Relief Organization)
CCMS	Comite de Coordination de Mobilisation Sociale (Committee for Coordination and Social Mobilization)
CHD	Centre Hospitalier de District (District Hospital)
CSB	Centre de Santé de Base (Health Center)
AMM :	Agence du Medicaments de Madagascar (Drug Regulatory Authority)
DPLMT	Direction de la Pharmacie, des Laboratoires et de la Medecine Traditionnelle (Directorate of Pharmacies, Laboratories, and Traditional Medicine)
DULMT	Direction des Urgences et de la Lutte Contre les Maladies Transmissibles (Directorate of Emergency Medicine and the Fight Against Infectious Diseases)
DSF	Direction de la Santé de la Famille (Directorate of Family Health)
EML	Essential Medicines List
GAIN	Groupe D'action Intersectoriel Pour la Nutrition (Intersectoral Group for Nutrition Action)
MCDI	Medical Care and Development International
MINSANPF	Ministère de Santé et du Planning Familial (Health and Family Planning Ministry)
MOH	Ministry of Health
OTC	Over the Counter
PCIME	Prise en Charge Intégrée de la Maladie de l'Enfant (IMCI)
PSI	Population Services International
PHAGECOM	Pharmacie à Gestion Communautaire (Community Pharmacy)
PHAGDIS	Pharmacie de Gros de District (District Depot)
SALAMA	Central d'achat des Médicaments (Central Pharmacy Agency)
SIECMS	Service de l'Information-Education-Communication et de la Mobilisation Sociale (IEC and Social Mobilization Service)
SIG	Système d'information et Gestion (Management Information Systems)
SPC	Service des Participations Communautaires (Community Participation System)
SSSa	Service des Statistiques Sanitaires (Service of Health Statistics)
SSD	Service de la Santé de District (District Health Service)
SSEA	Service de la Santé de l'Enfant et de l'Adolescent (Service of Child and Adolescent Health)
U5	Under five years old
UPSM:	Unité de Production des Solutés Massifs (Unit for the Production of High Volume Solutions)

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Executive Summary

A five-person team visited Madagascar from September 27 to October 7, 2005 to assist the Ministry of Health (MOH) and its partners in moving forward with the introduction of zinc for the treatment of diarrhea. The team met with key stakeholders in the MOH, donor community, UNICEF, WHO, cooperating agencies and projects, and the private sector; conducted field visits to Tuléar II and Toamasina; and met twice with the Zinc Technical Committee to develop a draft action plan for zinc introduction in the next year.

Diarrhea prevalence and treatment

The prevalence of diarrhea reported for a two-week period in children under 5 years of age in Madagascar is 10% (DHS 2003). There was substantial variation in reported prevalence across provinces, the highest being Toliara (21%) and the second highest being Toamasina (11%). Antananarivo and Fianarantsoa had the lowest prevalences (6%). Use of health facilities for diarrhea treatment is low; only about one-third of children who were reported as having diarrhea were taken to a health facility for treatment. Use of prepared ORS is also low (only 12% of all children with diarrhea were treated with prepared ORS), while use of home-prepared solutions (*solutions maison*) is about three times as high as ORS. Survey data did not report on the use of antibiotics or other medications for diarrhea treatment. However, in the team's visits to both formal health facilities and private pharmacies, these inappropriate treatments often seem to be preferred.

Opportunities for introducing zinc in the treatment of diarrhea exist in the expansion of IMCI, the anticipated inclusion of treatment and preventive C-IMCI in the roles of community health workers, and the potential role of the private sector. Sixty percent of health workers have been trained in IMCI, which has been introduced in 101 of 111 health districts. ORS is available in 80% of the sites. In the near future, follow-up training is planned for the IMCI district point persons, who ensure the retraining and updating of health workers previously trained in IMCI. Revision of the IMCI curricula and other training materials should include changes in treatment guidelines for zinc, malaria, and HIV/AIDS. Numerous service delivery points exist, including public health facilities, private providers, and social marketing channels. The potential for adding zinc and ORS to the existing line of subsidized, socially-marketed products appears to be especially strong.

Health information system

Madagascar has a computerized health information system operational at the district level that includes health facility and hospital data. For diarrheal diseases, the system is currently restricted to data on the number of cases treated and the stock of ORS. The system was recently revised to incorporate different program data needs on fewer reporting forms, and there is space on these revised registers to accommodate new data such as quantity of zinc stocked and used for diarrheal disease case management at health facilities.

Pharmaceutical management

Including zinc on the Essential Medicines List and registering it as an over-the-counter medication are necessary first steps in implementing a zinc policy in Madagascar and ensuring its availability through the currently available procurement and distribution

channels. Based on the established procedures existing in the country, this should be feasible in a relatively short space of time. Procurement procedures and practices exist at SALAMA, the public sector pharmaceutical procurement agency, to ensure that sufficient stocks of zinc and low osmolarity ORS are available at the central level for distribution to district depots. Weak capacity at the district and health facility levels for quantification of zinc and ORS requirements, and for inventory and store management may affect the availability of these products at the peripheral level health facilities. Training of district depot managers and dispensers at the health facilities in good pharmaceutical management practices is required. The private not-for-profit sector in the country is fairly strong, with a nationwide network that complements the services available in the public sector, and is the only sector that currently distributes pharmaceutical products at the community level. The private commercial sector is stronger in urban areas compared to rural areas, but dispensing practices within this sector may be problematic. It may be necessary to strengthen the capacity of the Directorate of Pharmacies, Laboratories, and Traditional Medicine (DPLMT) and the Drug Regulatory Authority (AMM) to provide the required regulatory oversight of the pharmaceutical sector.

Behavior Change Communication

Madagascar has developed innovative approaches to addressing multiple causes of child mortality through behavior change communication (BCC) and community mobilization. These strategies support the delivery and use of a package of integrated services and improved family practices. BCC is an inherent component used by the MOH and its partners, who have communications departments responsible for producing materials, such as radio spots, TV ads, and posters relating to vitamin A supplementation, malaria, etc. For example, PSI is involved in various social marketing campaigns (such as bed nets and Sur'eau) and has in-house lay-out specialists and graphic designers who produce state-of-the-art communications materials. Materials present at the national level include a booklet with the IMCI algorithms for actions for children aged two months to five years, several posters on the prevention and treatment of diarrhea, the child health card, counseling cards, and gazettes that are published with different themes relating to child health and nutrition. There are several main messages and corresponding pictorial images for diarrhea prevention and treatment that are specified in the IMCI materials as well as in the counseling cards, and used by all organizations producing BCC materials.

The national coordination mechanisms, district, and community-level capacity in BCC provide an opportunity to effectively introduce zinc therapy. Health facilities at the district level are equipped with the materials (posters, counseling cards, and IMCI algorithms). At the district level, there is a wealth of NGOs active in child health and nutrition activities, with a strong capacity for social mobilization (such as ASOS, ADRA, etc.). In a review of the IMCI program conducted in 2000, one of the advantages of activities aimed at improving community- and family- level practices is that various IEC materials exist at the community level. Field visits during this assessment found that the counseling cards are available at the community level, and mothers observed at the health facilities had their child health cards. There are a myriad of community-level NGOs using innovative BCC approaches. These include MCDI, ASOS and ADRA. One of the most innovative approaches is the *Kominina Mendrika* or Champion Community approach, spearheaded by Santénet and currently in use by many of its partners.

Highlights from the action plan

- There is a strong commitment by the MOH to rapidly move forward with the registration of zinc as an over-the-counter drug on the essential medicines list
- The stakeholders agreed to phase in the introduction of zinc in three districts in the three regions of Madagascar with the highest prevalence of diarrhea
- The MOH will finalize the draft action plan, develop budgets for specific action steps with partners, and seek donor support to begin this pilot in three districts.
- The pilot implementation will be carefully monitored and evaluated so that lessons learned can be used to inform scaling up zinc treatment.

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1.0 Introduction

In April 2005, USAID/Madagascar requested technical assistance from the BASICS Project for the introduction of Community-Based Treatment of pneumonia and diarrhea, and of zinc for the treatment of diarrhea. In preparation for this assistance, Dr. Adam Slote, Child Health Advisor in the Global Health Bureau, visited Madagascar in May 2005 to conduct a preliminary assessment of the need and feasibility of introducing both interventions, increase understanding of the interventions within the Ministry of Health (MOH) and its key donor and implementation partners, and propose recommendations for next steps in the introduction process. Dr Emmanuel Wansi, BASICS Senior Technical Officer for ARI/CDD, followed with a visit that resulted in the creation of a subcommittee to lead the introduction of the two interventions.

While these visits were focused on Community-Based Treatment, it was evident that Madagascar is a promising candidate for population-level introduction of zinc for the treatment of diarrhea:

- The MOH is eager to proceed and is willing to lead the process. Towards this end, it created two committees: a Child Survival Steering Committee (chaired by the Minister of Health or, in his absence, the Secretary General) and a Technical Committee (focused on zinc and community treatment of ARI, and chaired by the Director of Family Health);
- The President of the IMCI Ethics Committee—the most senior pediatrician in the country—has indicated her support for zinc for treatment of diarrhea. This support is likely to be shared by the remainder of the pediatric community;
- The donor community (USAID, UNICEF, WHO and the World Bank) has indicated its commitment to supporting the MOH for this intervention;
- Numerous service delivery points exist, including public health facilities, private providers and social marketing channels. The potential for adding zinc and ORS to the existing line of subsidized, socially-marketed products appears to be especially strong.

Several steps have already been taken:

- Zinc is referred to in the national nutrition policy and the MOH has expressed a desire to add it to the child health policy;
- UNICEF had formed a task force to develop a protocol to study issues related to the introduction of zinc in public health facilities;
- UNICEF has pledged to purchase a sufficient supply of zinc and low-osmolarity ORS to last for the first few years of implementation.

With the advocacy phase largely complete, the purpose of the zinc assessment was to assist the MOH and its partners in moving forward with the introduction process. The specific objectives of the visit were to:

1. Strengthen the capacity of the Madagascar MOH and its key partners for introduction of zinc for treatment of diarrhea
2. Assist the MOH and its key partners in developing a strategy, plan and timeline for introduction of zinc
3. Develop a draft zinc assessment tool for future use in other country settings

The team was expected to produce a final report, including comprehensive assessment and recommendations, as well as draft zinc assessment tool for future use in other country settings.

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2.0 Methodology

2.1 Participants

The assessment was a collaborative effort between a team of external technical assistants and the Madagascar ad hoc technical committee for child survival. The external assessment team was jointly led by Eric Swedberg and Emmanuel Wansi from BASICS (team leaders), working in conjunction with Grace Adeya from the RPM Plus project, Micheline Nturu from HKI, and Philip Harvey from MOST/A to Z. Jane Briggs of RPM Plus played an active role throughout the process. The Madagascar technical committee for child survival was led by Dr. Rahantanirina Perline, Director of the MOH's Family Health Division. Dr. Rakotomanga Raymond, head of the Child and Adolescent Health Unit, coordinated the smaller MOH team working closely with the external technical assistants. The Madagascar team included:

- *MOH Child and Adolescent Health Division*
 - Dr. Rakotomanga Raymond, Division Head
 - Dr. Vony Soa Hanitra, Head of the Child Health Unit
 - Dr. Ravelomanantsoa Félicie, point person for the Zinc/IRA project
- *MOH Nutrition Division*
 - Dr. Rakotonirina Simon, Chef de Service de la Nutrition au Ministère de la Santé
- *Other Government of Madagascar Stakeholders*
 - Dr. Tafangy Philémon, Malaria/Directorate for Emergency Medicine and the Fight Against Infectious Diseases (DULMT)
 - Dr. Noro, Directorate for Health District Development
 - Prof. Serge Gottot, National Institute of Public and Community Health
 - Prof. Ravelomanana Noeline, Director of the Antananarivo Mother and Child Teaching Hospital
 - Prof. Raobijaona Honoré, University Hospital Center, Mother and Child Unit
- *Technical and financial partners*
 - Dr. Razanatsoa Angeline, WHO
 - Dr. Rabarijohn Norolala, UNICEF
 - Dr. Raharison Serge, SantéNet
 - Dr. Priscilla Raelina, LINKAGES
 - Dr. Joséa Ratsirarson, MCDI
 - Dr. Rakotomalala Rémi, CRESAN

The most active members of the national team included the Child and Adolescent Health Service, SantéNet and PSI.

2.2 Activities

The assessment scope of work (see Annex 5) specified the key questions to be addressed during the assessment. The assessment process and team's activities are described in sections 2.2.1 and 2.2.2.

2.2.1 Preparation

Preparations for the assessment began in early September 2005 and the in-country activities took place between September 25 and October 7, 2005. Preparations included activities carried out by the Madagascar country team and those by the external team. The external team developed the approach, data collection tools and provided input to the country team. The country team carried out the desk review, selected areas for the field visit and prepared a plan of activities, including setting appointments for the key informants to be interviewed. The external team held a conference call with the Washington D.C.-based team members, who gathered at the BASICS office and exchanged regularly through email and phone calls with the country team. Content of the teleconference included briefing team members on Madagascar health systems and relevant activities to the assessment, reviewing the SOW, distributing assessment sections among team members and agreeing on next steps.

Most team members had read the report from a similar assessment in 2005 in Tanzania and maintained contact with the authors, Rolf Klemm and Peter Winch. Grace Adeya from RPM Plus also spoke to Karim Smine of USP, who had extensive information on Madagascar. During the preparatory phase, some team members attended a meeting in Washington with Nutriset, the main manufacturer of zinc dispersible tablets.

The extended team also held two teleconferences with the team in Madagascar on September 19 and 23. The first included a discussion of sites for the field visits, identifying key informants (a suggested list was sent to the country), the status of the desk review (questions were sent to guide the desk review), developing the questionnaire (a draft was sent for the in-country team to provide feedback) and other logistical issues. The second conference call dealt with the status of the desk review and finalization of planning for the site visits. The team decided to visit two sites based upon the following selection criteria:

- high diarrhea prevalence;
- areas of poor accessibility to services;
- ease of accessibility by the team; and
- partner presence to facilitate logistics and planning.

A draft data collection tool was developed by the combined team members in preparation for the in-country interviews and field visits. This tool included guidelines for (a) group discussions, (b) in-depth interview questions for key informants, and (c) a desk review. The assessment explored: MOH policies and the legal framework related to current and potential product availability in country; key diarrhea prevention and treatment issues and standard treatment guidelines; drug management, including procurement, distribution, inventory management; IEC/BCC approaches, including mass communication, community mobilization, education and counseling; human resources, including training (pre-service, in-service), supervision, quality improvement, health

information systems, and opportunities and needs for operations research; the private sector's role, including for-profit, subsidized social marketing, and non-profit; as well as financing and sustainability (see Annex 7).

Assessment Steps:

- Assembling the assessment team
- Planning activities prior to in-country visits
- Undertaking a desk review of epidemiology and service statistics
- Developing a checklist and topic guide
- Collecting data at the central level
- Collecting data in peripheral sites
- Validating field site findings
- Analyzing data
- Presenting team findings and developing a draft action plan
- Debriefing donors and completing the report

In addition to the conference calls, contact between the external and country assessment teams was maintained through e-mail. The Chemonics bilateral project, Santénet, played a leading role in setting up the teleconferences and also centralizing e-mail exchange with the MOH. This was important because the MOH has limited access to Internet and limited resources to print materials. Communication difficulties prevented the participation of the HKI team member during the conference calls.

2.2.2 In-country Activities

On the first day, the external team members met the key members of the MOH Division of Family Health. The week's schedule of visits, including the field visits, was finalized and is presented in Annex 2. Courtesy visits were made to WHO, UNICEF and USAID to improve planning and data collection. The list of stakeholders from these and other organizations who were met during the assessment team visits in Antananarivo is included in Annex 1. Following these initial visits, the external team and in-country team members divided into subgroups, largely according to their areas of expertise. Grace Adeya focused on pharmaceutical management, Micheline Nturu focused on the BCC component, and Phil Harvey focused on case management. Eric Swedberg and Emmanuel Wansi focused on health information systems, financing, human resources, and other general issues.

The sequence of activities in Madagascar was as follows: interview of key informants in Antananarivo; a first meeting with the technical committee to discuss the strengths, weaknesses and opportunities for the introduction of zinc treatment; travel to the regions, additional interviews in Antananarivo; discussions of findings; and planning of next steps (see Annex 2 for the schedule). This sequence was chosen to enable the team to collect any additional information prompted by the field visits, and to catch up with any major key informants that might have been missed during the first round in Antananarivo. In all situations, key informants were informed before the arrival of the

team. In almost all cases, nationals accompanied external team members. Except for the field visits, the nationals regularly changed because of concurrent activities that required their participation.

Group discussions organized during the first week to collect information from members of the Child Survival Technical Committee generated very good information on strength, weaknesses, and opportunities of the system for control of diarrhea activities. The meeting was led by the Director of Family and Child Health, Head of the Child Survival Committee (see Annex 3 for a list of participants). The committee members were divided into three subgroups based on area of expertise to discuss and present their findings on: (1) case management; (2) pharmaceutical management; and (3) advocacy and behavior change. There were more than 30 members and resource persons present.

For the field visits, the external assessment team was divided into two groups each including a representative from the MOH and each guided by a local staff member. At the peripheral level, the team had discussions with the persons in charge of the regions, districts, CSBs (*Centre de Santé de Base* or health center), NGOs, and Fokotany (the lowest administrative division of the community) in three districts of Tamatave and two districts of Toliary. Where possible, they visited PhaGdis (district depots) and PhaGcoms (community pharmacies). At the community level, focus group discussions were held with village health workers, community leaders, and parents. In-depth interviews started at the regional level, then moved to the district level, and finally continued at the community level, where the team met various players, including users, leaders, providers, and NGO staff supporting community-based activities. Translation into Malagasy was required at the community level, though some volunteers could speak French. (see Annex 1 for a list of persons interviewed) Whenever possible, a debriefing was provided to the district and regional team. In fact, one regional team requested a presentation on zinc. There were questionnaires for each category of facility or actors.

Upon return to Antananarivo from the field visits, more interviews were carried out to complement information from the field, as well as with some key informants who had not yet been interviewed. The team also undertook a series of meetings with key staff at the DSF (Directorate of Family Health) to discuss and validate their observations and conclusions from the field.

On October 6, the assessment team presented preliminary findings to the Zinc Technical Committee. This meeting was attended by 30 persons at the Santénet office conference room and included representatives from the Ministry of Health, UNICEF, USAID and NGO partners (see Annex 4 for a list of participants). Following discussion of the team's findings, an outline of the main steps to consider for the introduction of zinc in Madagascar was presented. These steps were divided into: (1) pharmaceutical management; (2) case management of diarrhea; and (3) advocacy and behavior change. The larger group divided into three smaller working groups to discuss the approach for each component and then presented their recommendations to the larger group. Groups proposed solutions to address problems and concrete actions to introduce zinc. During the plenary session, a work plan, including a timeline and responsible persons and agencies, was developed. The next step will be report dissemination, followed by detailed planning for implementation. Detailed implementation planning will take place after the MOH has identified the sources of funding for the introduction. One issue to be addressed is the cost of zinc. MOH partners have diverging views on the cost of and access to zinc, some being in favor of free treatment. The team ended the mission with a debriefing to USAID.

2.3 Observations on the Methodology and Recommendations for Next Application

Timing and resources for the desk review

The desk review needed extensive work that could not be carried out by Ministry of Health staff. In the future, it is recommended that a consultant or a partner with experience, time and communication resources be identified to do the desk review. It is important to start the review very early so that the assessment team can effectively use the information for planning field visits.

Condensing the interview guides

One of the objectives of the assessment was to develop a draft zinc assessment tool which can be adapted for future use in other countries. The team began by developing questionnaire guides for interviews and field visits. The team first developed questions for each topic area based upon the scope of work and then merged these questions, as appropriate, for persons and organizations concerned with multiple topics. For example, District Health Officers had in-depth interviews covering several topic areas. Merged question guides turned out to be lengthy. Merged questions for a single respondent or to be asked by a single interviewer should be reduced to the strict minimum (not more than 1 hour). Although there was an attempt to limit the data to be collected in a merged questionnaire, more reduction is needed.

Planning for presentations

Contrary to what had been anticipated, there was interest in the field in knowing more about zinc and its effects. No presentation or materials were ready for the peripheral level and, accordingly, no time was planned for the presentations. However, the team was requested to make presentations in the field and respond to technical questions. In the future, the assessment team should include these presentations in the planning phase and prepare technical materials for handouts.

Interview organization

Most health facilities were run by one health staff member, who then had to answer most of the questions. In such a case, only one questionnaire could be covered at a time, making the second member of the team less productive. In similar cases, team members should work separately; one could go to the community while the other is working at the health facility. This would have been possible in Madagascar because facilities play a limited role, if any, in community-based activities and, if there is another health facility staff member, it would also be possible to supervise community-based activities.

Selection of field sites

Criteria to select areas for field visits were not specific and best performing districts were selected, thus providing information that cannot be generalized across different districts. In fact, a health facility not initially planned for the visit, but randomly selected, provided information much different from those obtained from the facilities scheduled for visits. Seeing the best facilities is important, but visiting the less performing ones is equally important because they provide complementary information.

Scheduling of Site Visits

Concurrent activities affected the availability of material and human resources for the assessment. Planning in advance with some flexibility, but also monitoring the scheduling of some important events is necessary to avoid conflicting activities and also to take advantage of scheduled activities. For example, a meeting of all regional health and key MOH officers was planned just around the assessment. This was a golden opportunity to inform and learn from key personnel in the field.

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3.0 Findings

3.1 Diarrhea Prevalence and Treatment

3.1.1 Prevalence

Data on the contribution of diarrhea to morbidity and mortality in Malagasy children are available from the Government's routine health information system, DHS, and MICS. The *Annuaire des Statistiques du MINSANPF* in 2003 indicated that 14% of consultations at public health facilities for children under 5 years of age were for diarrhea treatment. Malaria and ARI were more common reasons for consultations (34% and 22% respectively). Diarrhea was the second highest cause of mortality among children in hospitals (18%) following malaria which resulted in 25% of the mortality.

The prevalence of diarrhea reported for a two-week period in children under 5 years of age in the 2003-04 DHS survey was 10%, compared to 13% in the 2000 MICS survey. As is common, the highest proportion was in children age 6 to 11 months (19%) and 12 to 23 months (17%). There was substantial variation in reported prevalence across provinces, with the highest being 21% in Toliara and the second highest in Toamasina (11%). Antananarivo and Fianarantsoa had the lowest prevalences (6%). Among children 6 to 24 months of age in Toliara and Toamasina, it is likely that more than one-third and one-fifth respectively experienced diarrhea during the two week period covered in this survey. Given geographic disparities in diarrheal disease prevalence, the zinc intervention should prioritize those areas with the highest prevalence rates.

Previous DHS surveys were undertaken in the country in 1992 and 1997. The reported prevalence of diarrhea in the two weeks prior to the survey was higher in 1997 than either of the other two surveys. The comparison of overall prevalences of diarrhea reported in three DHS surveys is not valid because the 1997 survey sampled younger children than in the other two surveys (under 3 years rather than under 5 years). Because younger children experience more frequent episodes of diarrhea, the overall rate in 1997 can be expected to be higher than the other two surveys. However, comparing age-specific rates across the three surveys (see Table 1) indicates that diarrhea was more common in 1997 than in either of the other two surveys.

Table 1. Prevalence of reported diarrhea in the two weeks preceding the DHS and MICS surveys in 1992, 1997, 2000, and 2003, by age group

Age in months	Prevalence of reported diarrhea in two weeks preceding interview			
	1992	1997	2000 (MICS)	2003
< 6	12	15	9	6
6-11	23	33	25	19
12-23	20	33	19	17
24-35	12	25	11	10

3.1.2 Treatment of Diarrhea

Nationally in the 2003-04 DHS survey, about two thirds of mothers were aware of ORS for the treatment of diarrhea. The lowest level of knowledge by far was in Toliara (38%). As expected, there were strong associations of this knowledge in mothers with higher levels of education and urban residence.

Information about the treatment of diarrhea in the 2003-04 DHS survey is shown in Table 2. About one-third of children sampled (32%) in the latest DHS survey who were reported as having diarrhea were taken to a health facility for treatment (Table 2). Of the children with diarrhea, only 12% were treated with prepared ORS while about one-third were treated with home-prepared solution (*solution maison*).

Table 2: Percentage of young children reported as having diarrhea in the previous two weeks who were taken to a health facility for treatment and who were treated with either sachets of ORS or with home-made rehydration solution (DHS 2003)

Characteristic	% Taken to Health Facility	Oral rehydration solution	
		Sachet	Home Solution
Total	32	12	32
Male	27	16	30
Female	38	8	34
Urban	41	23	27
Rural	30	10	33
Toamasina	29	10	10
Toliara	35	10	53

Comparisons with previous DHS surveys on the treatment of children with diarrhea are made difficult by circumstances in which the data were either collected differently in each survey or the results were presented differently in each report. For example, in 1992 the reported result is the, "Percentage of children with diarrhea taken to health facility or a doctor". In 1997, in addition to surveying younger children, the result presented is the, "Percentage of children with diarrhea for which a consultation (was made)." In 2003, it was the, "Percentage of children taken to a health facility".

The use of ORS sachets and home-prepared solutions was standardized across the surveys. However, comparing these results does not reveal a clear trend. For ORS sachets, there was little difference between 1992 and 2003, but use in 1997 was substantially higher. On the other hand, use of the home-made solution was substantially higher in 2003 than in the two previous surveys. It is remarkable that more than half the children with diarrhea in Toliara province were treated with *solution maison*. Also remarkable are the very low rates (almost zero) reported in 1997. But these numbers, together with the higher rates of ORS sachets reported in 1997, give some cause to question the validity of these data, or at least suggest that they warrant further exploration to establish validity.

Table 3: The treatment of diarrhea with oral rehydration therapy reported in the MICS 2003 survey and three DHS surveys in U5 children in 1992 and 2003, and under 3 years in 1997 for the entire country and for the two regions with the highest diarrhea prevalence visited during the assessment.

Characteristic	Oral rehydration therapy							
	ORS Sachet				Other Home-based Solutions			
	1992	1997*	2000	2003	1992	1997*	2000	2003
Total	14	23	22	12	15	1	11	32
Male	15	23	21	16	16	1	10	30
Female	13	23	24	9	14	0	11	34
Urban	23	42	29 ¹	23	23	2	13	27
Rural	13	18	21	10	14	1	9	33
Toamasina	11	28	19	10	6	0	5	10
Toliara	10	15	22	10	10	2	5	53

* Children aged 0-35 months only

Rehydration with either factory-prepared oral rehydration salts (ORS) or home-made sugar salt solutions has long been the standard treatment for diarrhea. The product was manufactured locally by UPSM, a government agency that ceased production a few years ago. Since then, supplies have usually been procured through UNICEF Copenhagen and are believed to be generally adequate to meet current demand. There are currently efforts being made to restart production at the UPSM facility.

The challenge for introduction of zinc treatment of diarrhea is that there is low use of oral rehydration salts (12%) and although there is a higher use of home-based solutions (32%) for diarrhea therapy, less than 50% of diarrheal disease episodes currently receive ORS or ORT. Furthermore, less than 1/3 of children with a diarrheal disease are taken to a health facility for care. To successfully introduce zinc for children in need, it is necessary to better identify cases of diarrheal disease and ensure that these children receive appropriate care.

3.1.3 Recent Initiatives and Issues: Control of Diarrheal Disease

In 1995, Madagascar became the first francophone African country to adopt IMCI, building on previous gains made in the control of diarrheal disease. IMCI evolved from an initial pilot in 16 sites in two districts between 1996 and 1998, and then went to scale in all sites in 20 districts under Jereo Salama Isika and LINKAGES. The protocols for treatment of diarrhea in children are specified through the IMCI program. The IMCI program introduced the components of training, health systems, and community. The assessment team examined the case management findings according to medical facilities, the private system, and community level. The assessment team also examined

¹ Other urban areas besides the capital city.

the health information management system with regard to diarrheal disease case management and explored the issue of financial access to treatment.

Facility Treatment

The facility-based training component was introduced nationally in 1999 and has now been implemented in 101 of 111 health districts. Initially, an 11-day training curriculum was instituted, but this was found to be too long to be sustainable. In January 2000, the MOH suspended all forms of formal health worker training, including IMCI. Reasons for suspension included the prolonged absence from health centers already short in staff (a problem that was further aggravated by the introduction of cholera to Madagascar, requiring 24 hour availability of health staff at their facilities) and the high cost associated with formal training (US\$ 500 of direct cost per trainee). An assisted self-learning approach *Auto Apprentissage Assisté* (AAA) was introduced for health workers in 2000. Key steps were taken to address reduced time for practice, e.g., spacing courses over several months and extending monthly sessions from one day to 3-5 days to provide more time for practice.

A six-day training curriculum is currently being implemented. Pre-service training in IMCI protocols has been implemented in medical schools since 2000 and in nursing schools since 2002. A second review of the IMCI program undertaken in April 2005 estimated that 60% of health workers have been trained in IMCI. For the remaining 40% of health workers a more in-depth training in diarrheal disease management is needed in addition to the zinc specific training component. In the decentralized health system in Madagascar, the districts are responsible for ensuring that health facility staff receive training in IMCI, and the central level IMCI focal point arranges for technical support if requested. In the near future, training in follow-up is envisioned for the IMCI focal points of the districts (111), who will then be responsible for the retraining and updating the skills of health workers previously trained in IMCI. Revision of the IMCI curricula and other training materials is envisioned to include changes in treatment guidelines for zinc, malaria, and HIV/AIDS.

Facility-level supervision is supported by a guide for standard IMCI supervision. Follow-up supervision of IMCI training has been coordinated by provincial IMCI coordinators in the past. Now the districts are responsible for the ongoing IMCI supervision (action plan, financing). Due to these changes in supervision responsibilities, supervision has been weak and the recent IMCI review noted that district management teams were not properly supervising health facility IMCI activities. This lack of supervision is a concern because the introduction of community case management including the community based treatment of diarrheal diseases requires close supervision from the health facility, especially during the early phases of implementation.

Application of the standards of IMCI was found to be inconsistently applied in the sites visited by the assessment team. For example, the assessment team observed the use of Cotrimoxazole for treating simple diarrhea and a low-use of ORS for the treatment of dehydration. In the sites visited, there was also weak functionality of ORT corners even when the material for the corners existed.

Private Sector

Numerous service delivery points exist beyond public health facilities, including private providers and social marketing channels. The potential for adding zinc and ORS to the existing line of subsidized, socially-marketed products appears to be especially strong.

PSI collected information on mothers' knowledge of causes of diarrhea in its national health behavior tracking survey in December 2004. They found that 65% knew that contaminated water was a cause of diarrhea (75% in urban and 62% in rural areas). This survey also assessed knowledge of and behaviors related to the PSI water purifying product, SurEau. Results indicated that knowledge of the product was high, but that women in urban areas were much more likely than rural women to know where to purchase it (83% versus 47%) and to have used it (39% versus 21%). This rural/urban discrepancy is likely due to differentials in education, access to information, number of delivery points and economic access to SurEau.

Community

There are numerous programs and organizations supporting community health volunteers in Madagascar. Almost all of these community programs promote the use of rehydration therapy as a first approach to treating children with diarrhea. Training curriculums for community health promotion exist and were validated nationally in 2003. Separate curriculums exist for training community health volunteers in the use of Palu-Stop in the treatment of malaria, FP products and SurEau. According to the recent IMCI review, 19% (337/1999) of health centers are implementing a preventive C-IMCI approach. There are several messages for diarrhea prevention and treatment that are specified in the IMCI materials, as well as the counseling cards, which have corresponding pictorial images. These can be summarized as: (1) mother/caretaker continue to breastfeed; (2) boil water; and (3) give your child foods, particularly those they prefer. In addition, the danger signs that necessitate a health clinic consultation are described as presence of blood in the stool, child unable to drink, has lethargy or vomiting, or has diarrhea for 3 consecutive days.

Revision of the curriculum for trainings community agents is envisaged. Supervision of IMCI includes C-IMCI, however there is no guide for monitoring CHWs. The assessment team noted weak quality assurance (absence of observation and supervision of CHW performance). However, clear standards for certain activities exist and there is support for volunteers, including meetings and visits on the ground.

Financial Access

A number of initiatives have been introduced in Madagascar to improve financial access to health services, ranging from insurance-type schemes to the Bamako initiative. The Swiss aid agency has operated a network of cooperatives in which member contributions were used to purchase drugs. The government is currently establishing a system of equity funds to address the financial access issues of the poorest segment of the population. A small portion (3/135) of the income of routine medicine sales from health facilities is to be put into a separate bank account. This fund may also be supplemented by other fundraising at the village level. A list of indigents is then established by the village leaders or mayors. The people on the list or emergency cases can then purchase their medications with a voucher (*bon de service*). At the end of each month health centers are reimbursed for vouchers they accepted by the treasurer of the management committee overseeing the equity fund. During the field visits the assessment team noted that these funds are newly established in some sites, but are not yet fully functional. Until these funds are fully functional, they will not improve financial access to zinc and ORS.

Health Management Information System

Madagascar has a health information system partly computerized since 1998. The system has four components:

1. Vital data and family planning activities data
2. Routine activities data
3. Epidemiologic surveillance data
4. Administrative data, including human resources

Vital data are those mostly collected throughout the system, including the community level (Fokotany), where births and deaths are registered. Family planning is the only community-based activity in which data are incorporated into the health center report. It is possible to build further data including community-based treatment of diarrheal diseases into the health center reports in a similar fashion.

Routine facility data are used for monthly reports and epidemiologic surveillance. Monthly reporting forms are standard for all facilities of the same level, public or private. New programs have created forms for their needs. An evaluation showed that a health facility completed 18 reports per month. There is an effort to integrate all the data needs into the monthly report form. The commission tasked with reviewing the forms recently modified the contents and guidelines, and a nationwide refresher training is planned update health personnel on data collection requirements and forms. Presently, data is collected on the number of diarrheal disease cases treated and the health facility stock of ORS. This data should be supplemented to include the number of diarrheal disease cases treated with zinc and health facility stock of zinc. It would be ideal to make these additions to the collection forms and training curriculum prior to the nationwide training of health personnel so as to avoid an additional training uniquely for zinc.

For epidemiologic surveillance, routine data are analyzed for any abnormal increase that triggers investigation. Medical officers were trained to analyze the data. Epidemiological cut points have been determined for each disease in the list of 22 that includes diarrhea, cholera, malaria and ARI. In fact, epidemiologic surveillance pointed to increased cases of diarrhea in the period preceding a 2001 cholera outbreak in Majunga. Similarly, there were higher figures before a 2002 flu outbreak in Fianarantsoa. In case of an outbreak, the district has to immediately inform the regional and central levels by any possible means. The surveillance network is made up of a multidisciplinary team from the various programs. The supervision of epidemiologic surveillance was recently moved to the Director of Emergencies and Disease Control.

Each month, each health center and facility completes one reporting form for the archive and two for distribution to the district. Most of the health centers' reports are brought to districts during monthly monitoring meetings. These meetings provide a systematic opportunity to discuss service issues and carry out refresher training. The district enters the data into a custom designed application and forwards one of the two copies as well as its synthesis to the province/region. Provincial and regional syntheses are sent to the Service of Health Statistics by e-mail or, for new regions not yet connected to Internet, on diskette. Each district is equipped with at least two computers.

The district Monitoring and Evaluation Officer analyzes data and makes recommendations to health facilities through quarterly feedback. There is no defined format for the report, but there is a list of elements to cover. There are indicators defined by level (health center, district and region). Feedback on the reports is sent by mail. The

regional and central levels previously provided feedback biannually, however this was stopped in 2002 for financial reasons. About 90% of private and public facilities complete monthly reports. Facilities in major cities account for most missing reports. Annual statistical reports for 2003 and 2004 have not been printed due to lack of resources. An evaluation of the statistics system showed that 12% of facilities computed indicators but did not use them. ORS stock out was reported by about 20% of health facilities. While the system provides data on cases treated and ORS stock management, these reports do not contain sufficient information for HMIS officers to assess the quality of case management by staff. Furthermore, since the forms were recently revised, they are reluctant to change them in the near future. However, there is space on the registers that can accommodate new data such as quantity of zinc stocked and used for diarrheal disease case management at health facilities.

Computer Applications

Health centers and district hospital monthly forms are computerized. However, the application designed in 1997 (with Access 3.0) is now outdated. Furthermore, some indicators have changed. A major overhaul is required. Two national MOH staff members were trained in the maintenance of the application and can do some limited work to meet updated needs. The application produces a health map showing health facilities and resources. The European Union will fund the development of applications for regional and specialized hospitals.

3.1.3 Group Work Recommendations for the Action Plan

Representatives from different ministerial, NGO, and UN agencies that are part of the Zinc technical committee discussed the above points and outlined the following action points that will form the principal case management activities related to the introduction of zinc as an adjunct therapy for diarrheal treatment (see the draft action plan in section 4.0 of this report for more details):

- Revise the IMCI algorithm to include zinc;
- Develop training curriculum for utilization;
- Select pilot sites, identify staff, and provide training;
- Revise data collection forms and IMCI supervision forms to include zinc stock and utilization; and
- Develop and implement rigorous monitoring and evaluation plans for pilot sites.

3.2 Pharmaceutical Sector Requirements for the Introduction of Zinc

3.2.1 Policy and Regulatory Requirements

Registration

In Madagascar, the decision on whether to register zinc as a medicine or as a nutritional supplement is important because it determines which organization would have oversight of its use. All medicines for use in the country, whether imported or manufactured locally, must be registered by the Drug Regulatory Agency, *Agence de Médicament de Madagascar* (AMM). While the regular registration procedures require that the company seeking to introduce the product in the county submit the request for registration to the AMM, a fast-track registration process exists for products required for MOH programs. This process requires that the product be included on the Essential Medicines List (EML) and the request for registration be submitted on behalf of the supplier.

Zinc, as a new MOH program product, would be eligible for this fast-track registration process (the process for obtaining this fast-track registration is outlined in the Action Plan in Section 4 of this report). No zinc products are currently registered by the AMM. The decision to register zinc as a medicine rather than a food supplement was made by the Technical Committee at the planning meeting held on October 6, 2005. During the meeting, it was also decided that zinc should be classified as a "Table C" product, which can be dispensed without a prescription, allowing for community distribution and for sale in the private sector. ORS products have already been registered by the AMM as Table C products and are available for sale in both the public and private sectors.

Essential Medicines List

The EML is revised every two years with the next revision scheduled for 2006. Between scheduled revisions, MOH programs can request temporary authorization for the inclusion of a product on the EML which can be granted from the Division of Pharmacy and Laboratories (DPLMT— *Direction de la Pharmacie, des Laboratoires et de la Médecine Traditionnelle*). SALAMA, the public sector procurement agency, is only authorized to procure products on the EML; hence, the importance of including all essential pharmaceuticals on this list if they are to be available in public sector health facilities. Products procured through SALAMA are tax exempt. ORS is on the EML, however no zinc products are currently included. To get zinc on the EML, the DSF needs to submit an official request for its inclusion to the DPMLT, who will then issue the required temporary authorization.

Quality Assurance

This AMM is responsible for ensuring the quality of all pharmaceuticals during the registration process and after their introduction into the market, as well as for developing and maintaining a pharmacovigilance system to monitor any adverse events that occur. However, the AMM's capacity for providing this oversight is constrained by insufficient equipment, and limited financial and human resources (e.g., the pharmacovigilance department is currently limited to one individual based at the central level). Due to the AMM's currently limited capacity, it is especially important to import zinc from a reliable source with high quality standards.

3.2.2 Procurement and Distribution

Public Sector

All public sector procurement and distribution is done centrally through SALAMA, a non-profit organization that has been contracted by the MOH to fulfil these roles. SALAMA is only authorized to procure items (both medicines and pharmaceutical supplies) on the EML. Procurement is normally done once a year through international open tenders. SALAMA develops the tender documents in consultation with the DPLMT and is responsible for selection of the successful bidders. It takes approximately 1.5 months from the time a tender is advertised to the selection of a successful bidder. After placing an order, the lead time to delivery is approximately 4 months. Procurement of items that are not included on the EML can be only done after submission of a special request to SALAMA by the MOH. All procurement done through SALAMA is tax free.

The procurement of pharmaceuticals for use in the public sector is financed by the MOH through a budget that the DPLMT holds and oversees on behalf of public sector health facilities, and by the use of funds generated as part of the cost recovery process at the district level. Each financial year, the DPLMT receives a predetermined budget from the government for the purchase of pharmaceuticals, which it uses to maintain a line of credit at SALAMA on behalf of the health facilities. The DPLMT is responsible for determining the line of credit that will be available for each health facility from this budget. When the health facility purchases a product that is on the EML from SALAMA, they draw down on their line of credit. The responsibility for determining how to allocate the line of credit to cover all the required products on the EML is the responsibility of each health facility, with oversight from the district health teams and the DPMLT. The health facilities can also use the money they generate as part of the cost recovery process to make additional purchases from SALAMA (and this is usually the only option available to them to make purchases at SALAMA once they have exhausted their line of credit). All medicines dispensed at public health facilities are sold at a margin of +35% of the SALAMA price.

As ORS is already on the EML², it is available for purchase by the health facilities through SALAMA using either of the financing processes outlined above. Currently, the low osmolarity ORS is not yet available through SALAMA. If zinc is included in the EML, then SALAMA would be able to procure it through the process outlined above, and it would also be available for purchase using the EML budget line or the cost recovery funds as occurs with other products on the EML. SALAMA is also authorized to sell to the private not-for-profit sector, including SALFA (the Lutheran Mission agency).

A distribution plan for delivery of pharmaceuticals to all 111 District Depots (PhaGDis—*Pharmacie de Gros de District*) is developed every December by SALAMA, in consultation with the PhaGDis and the district health teams. Distribution occurs every 3 months to the PhaGDis in accessible areas and every 6 months to the PhaGDis in non-hard-to-reach to private transport companies. These private transport companies are also identified through annual tenders.

² Introduction of the low osmolarity ORS is possible without any changes in the EML.

Private Not-for-Profit Sector

Two private sector agencies are involved in the procurement of pharmaceuticals for the private NGO sector, SALFA and Population Services International (PSI).

SALFA is the health agency for the Lutheran Mission in Madagascar. It is the only other major agency involved in procuring and distributing pharmaceuticals to a defined network of health facilities. The SALFA network consists of 27 health facilities nationwide. Procurement of pharmaceuticals is done through the head office in Antananarivo. Most of their procurement consists of direct purchases from pre-identified suppliers. Among these, IDA is their cheapest and most common supplier. Currently, all the products they procure are taxed at the point of entry. The tax is approximately 10%. SALFA has applied to the Ministry of Finance for tax-free status, which requires designation as an, "Agency of public health importance." Only the Red Cross and the Scouts currently have this designation. SALFA sells its supplies directly to the health facilities in its network at a +15 to 25% margin. The SALFA central warehouse at Antananarivo has limited storage capacity, equivalent to approximately a two month supply. Receipts are distributed to the health facilities as soon as possible after they arrive. This also means that SALFA does not have the capacity to sell to health facilities outside the network. Deliveries to the health facilities are contracted out to private transport companies, but SALFA also has a vehicle that is used occasionally for some deliveries.

PSI procures a limited number of products for distribution through its social marketing programs. It has classified these products in two main groups, depending on whether a prescription is required prior to dispensing the product:

1. Prescription-only Pharmaceuticals—PSI currently procures STI Kits and Depo-Provera on behalf of the MOH and other donor programs for distribution to private sector providers at a subsidized price. The items are distributed to NGOs, private sector pharmacies and private doctors through PSI-contracted pharmaceutical wholesalers. PSI determines the margins at which these items are sold to the consumers by these private providers.
2. Over the Counter (OTC) products: PSI currently procures Pilplan (oral contraceptive), Palustop (prepackaged Chloroquine), Sur Eau, Condoms and Long Lasting Insecticide treated Nets that are targeted for sale at the community level. These products are distributed through identified commercial wholesalers at the central level who are responsible for re-distribution to regional wholesalers. The regional wholesalers sell directly to the NGOs and other third party vendors primarily for sale at the community level. PSI provides training to the vendors to ensure that the items are sold as recommended.

PSI appears to be the main supplier of pharmaceuticals to the community through the social marketing programs described above. PSI is not currently involved in the procurement or sale of ORS or zinc, however it is exploring the development of a diarrhea kit that includes these two products for sale at the community level. Such a kit will potentially increase standardized treatment of diarrheal diseases at the community level, and adoption and subsidization at the national level will ensure that for every diarrheal disease case treated with the kit a sufficient dose is provided.

Private-for-Profit Sector

Several commercial private sector wholesalers and pharmacies are involved in the procurement and distribution of pharmaceutical products at the central and regional

levels. Most of these private sector providers are located in the major urban centers and their distribution networks are limited to these areas. These wholesalers and pharmacies should be encouraged to sell zinc and ORS, and counter agents should be trained in the proper use of zinc and ORS for the management of diarrheal diseases. Including the private-for-profit sector in efforts to introduce zinc will improve access especially in urban areas.

3.2.3 Quantification

Accurate quantification of requirements has been identified as one of the major challenges to the introduction of zinc in the public pharmaceutical sector. The pharmaceutical supply system in Madagascar is a “pull” system. Therefore, each health facility is expected to estimate its requirements and submit this to their PhaGDis. The PhaGDis collates the requirements for all the health facilities it supplies and submits the requirements to SALAMA, with a copy of the requests sent to the DPLMT. SALAMA has developed forms to support consumption-based quantification and these forms have been distributed to health facilities and PhaGDis by the DPMLT. However, to-date, none of the PhaGDis have correctly filled in these forms or been able to accurately quantify their requirements. Therefore, SALAMA has been unable to use the data provided for procurement decisions. DPMLT is responsible for the training of the public sector pharmaceutical workers in procedures of product management and quantification, but have not been able to do this. No separate Drug Management Information System (DMIS) exists to collect specific data relevant to pharmaceutical management that may assist in developing these estimates. The HMIS only collects stock-out data.

Given the challenges outlined above, SALAMA is doing its own estimates of need on the basis of past sales and data of expected disease incidence obtained through the HMIS. This has led to inaccurate estimates of pharmaceutical requirements, including ORS. At the time of the visit, SALAMA was concerned that most of its stock of ORS was about to expire, as they were not selling the quantities expected in their original estimates.

Estimating Zinc and ORS Requirements

Given the challenges outlined above, an accurate estimation of the requirements for the first year of implementing the zinc policy may not be possible. To obtain a rough estimate of the zinc and ORS requirements for the first year of implementing the new policy, certain assumptions about the population of children aged zero to four, the annual population growth rate, expected episodes of diarrhea per child per year, and expected care-seeking behavior were made. These assumptions are summarized in Table 1 below. The estimated mid-year population of children age zero to four in 2004 was obtained from the US Census Bureau’s International Database. The estimated number of diarrhea cases per child per year and the estimates of the percentage of patients seeking care in the public and private sectors were extrapolated from the results of the 2003 – 2004 DHS assessment³.

In this analysis, the use of the private sector includes anyone who sought care in the formal private sector health facilities and the informal private sector health facilities including retail outlets and traditional practitioners.

³ An explanation of the extrapolation was done can be obtained from Phil Harvey at AED.

Table 4: Assumptions Used to Estimate the 2006 Annual Requirements for Zinc

Base mid-year population for 0 - 4 age group in 2004 ⁴	3,111,179
Annual Population Growth Rate	2.8%
Number of diarrhea episodes per year per child	2.6
Percent of population with diarrhea targeted for ORS	100%
Percent of population with diarrhea targeted for treatment with zinc	100%
Number of ORS Sachets per treatment episode	2
Number of zinc tablets per treatment episode	10
Percent of cases seeking care in Private Sector	15%
Percent of cases seeking care in Public Sector	21%
Percent of cases with no care-seeking or seeking care in other sectors	64%
Estimated cost per sachet of ORS	US \$ 0.0524
Estimated cost per tablet on zinc salt	US \$ 0.0190

Based on these assumptions, the estimated requirements for the 20mg zinc tablets for the first year of implementation are approximately 85 million tablets at an approximate cost of US \$1.62 million (Table 5). An estimated 64% of the 85 million tablets are the requirements for those who do not currently seek any treatment for diarrhea and represent the potential target for any community-based intervention.

The estimated ORS requirements, based on the expected incidence of diarrhea in the population and assuming two ORS sachets are given for each diarrhea episode, are approximately 17 million sachets for the first year of implementation. This may be an over-estimation of requirements because current ORS consumption is very low. Based on the analysis of DHS data, only 12.6% of those who had diarrhea received ORS. Only 2.2% of those seeking care for diarrhea in the private sector received ORS and only 7% in the public sector.

Table 5: Estimation of the Requirements for Zinc and ORS in the First Year of Implementation

Care Seeking Sector	ORS (2 Sachet)		Zinc salt (20mg tablet)	
	Requirement	Est. Cost (US\$)	Requirement	Est. Cost (US\$)
Public Sector	3,530,328	\$ 184,989	17,651,643	\$ 341,081
Private Sector	2,564,518	\$ 134,280	12,822,594	\$ 243,629
Other	10,941,942	\$ 573,358	54,709,708	\$ 1,039,484
All Sectors (National)	17,096,788	\$ 895,872	85,483,945	\$ 1,624,195

The current plan for implementing the zinc policy is for introduction to begin in a few pilot districts, with additional districts phased in systematically until national coverage is achieved. The estimates in Table 5 gives an estimate of the total national requirements, but additional analysis would be required to make initial orders for the selected pilot districts and for phasing in additional districts. At this time, the pilot districts have not been selected and the plan for phasing in the remaining districts has not yet been

⁴ Source: The US Census Bureau's International database at <http://www.census.gov/ipc/www/idbprint.html>; Table 094: Midyear population by Age and Sex.

developed. Depending on the availability of data, several methods, can be used to estimate requirements once the pilot districts have been selected. If district-specific diarrhea incidence rates, health facility utilization rates, or district specific population figures are available, these can all be used to calculate estimates. The accuracy of each of these methods would depend on the accuracy of the data available. The estimated requirements for zinc for each district using available population figures is included in Annex 6. Table 6 below gives an example of estimated zinc needs and costs for one district in the region of Toamasina for a one year period. Applying the assumptions and calculations detailed above to the Brickaville district population of 25,777, the total cost to purchase sufficient zinc is \$13,718.

Table 6: Estimated Zinc Requirements and Costs for Brickaville District, 2006 (population = 25,777)

	Public	Private	Other	All
Estimated Requirements (Number of 20 mg Tablets)	151,617	108,298	462,070	721,984
Estimated Costs	\$2,881	\$2,058	\$8,779	\$13,718

The extent to which IEC campaigns and the training of care providers will increase uptake of ORS and zinc is uncertain at this time. For this reason, these potential increases in zinc uptake have not been taken into account for the purposes of the estimated zinc requirement calculations. It is recommended that a proper quantification exercise be completed three to six months after the implementation of the new strategy for more accurate estimates of ORS and zinc tablet requirements.

3.2.4 Storage and Inventory Management

The PhaGDis, which function as the district depots, are run by NGOs or other private sector providers under contract from the MOH. The contracts are issued to successful bidders following national open tenders and are awarded every three years. The DPMLT is responsible for overseeing the activities of the successful contractor. The contractors' performance is evaluated based on the specifications in the contract which provide a general outline of the financial and operational requirements that the contractor is expected to follow. No Standard Operating Procedures (SOPS) have been developed by the DPMLT to serve as guidelines for inventory management or storage practices expected of the contractors.

At the health center level, a community pharmacy (PhaGCom) serves as the dispensary. The PhaGCom is managed by a community health team that sits at the local government level. Staff at the PhaGCom generally have some high school education. Other than an orientation when hired, there does not appear to be any additional training provided to them.

As a result, the standards for inventory management and storage appear to depend on the contractor managing the PhaGDis or the staff and management team managing the PhaGCom. During the field visits, only one of the four PhaGDis visited was functioning well. Some of the problems identified included: poor record keeping, insufficient stock, excess stocks, products close to expiration, products left on the floor (despite the presence of empty shelves), and poor security of both the stock and the cash collected from the sale of the products. Given the small sample of PhaGDis visited, it is not clear how widespread these problems are. However, such shortcomings would need to be addressed in the long-term to improve the provision of services in the public health sector and ensure the success of the new zinc program.

At the community level, good inventory management practices appear to be more difficult to achieve. Most community health workers are provided neither with a box nor cupboard to store their products. They are not given advice on how best to store these supplies, nor is there adequate supervision of their activities or practices. Thus, it is easy to understand why they are not implementing good inventory management practices. Community health worker training curriculums should include drug management for childhood illnesses.

3.2.5 Rational Use

Public Sector

Although most of what is meant by rational drug use is dealt with under the section on treatment of diarrhea and IMCI, dispensing practices are also an important part of ensuring rational use of pharmaceuticals. The limited training and knowledge of the dispensers at the PhaGCom level is evident in the dispensing practices observed. During the visits to a few PhaGComs, no counseling was provided by dispensers to patients on the use of the medicines given; they simply sold the products prescribed to the patients. At some of the health facilities visited, the medicines were dispensed in rolled up pieces of paper with no written information, such as the name of the medicine, or written or pictorial instructions on how to take them. Pre-packaged medicines would be a solution.

Private Sector

The limited number of trained pharmacists in the country⁵ and the absence of trained pharmacy technicians mean that most private pharmacies are run by untrained individuals. This creates a problem in ensuring appropriate dispensing practices.⁶

⁵ The Schools of Medicine do not have a Pharmacy department therefore most of the pharmacists are trained in other countries.

⁶ During the visit to the Mahaboboka CSB in Tulear, an example of the poor and potentially dangerous dispensing practices by private practices was observed. A child with diarrhea had received a prescription from the doctor at the CSB a two days earlier. As the PhaGCom was closed at the time, the mother of this child had attempted to fill the prescription at a private pharmacy. The prescription was for ORS, Cotrimoxazole, Paracetamol, and Chloroquine (Total cost at PhaGCom: approximately 272 Ariary). The private pharmacy had altered the prescription and sold to the mother Smecta (diosmectita), Metoclopramide hydrochloride, chloramphenicol and an unidentified yellow tablet (Total cost: 2300 Ariary). The mother had returned to the CSB because her child was not showing any improvement.

Medicines are also available from non-regulated and undocumented outlets. The DPLMT has oversight of the private sector providers' activities, but it does not always have the capacity to provide the required supervision.

3.2.6 Local Production

FARMAD is a local private manufacturer. Import taxes on raw materials have affected its manufacturing activities, which it is now phasing out. It currently functions mainly as a wholesaler, working with manufacturers in Germany, China, Holland and Romania to produce products with the FARMAD brand for the local market. They have been working with PSI on its social marketing programs. FARMAD is responsible for the prepackaging of PSI products--particularly PaluStop--and distribution to wholesalers and private pharmacies. FARMAD is currently not importing or manufacturing ORS or zinc.

The MOH has a unit in charge of producing pharmaceutical solutions, the *Unité de Production des Solutés Massifs* (UPSM). They have just restarted production of the standard ORS formulation using raw materials they had in storage from the production of ORS in the past. The aim is to use these raw materials before they expire next year. The first delivery of ORS to SALAMA was sent the week of the visit (although it was not accepted by SALAMA because it did not meet labeling requirements). UPSM currently has the capacity to produce 700,000 sachets of ORS per year and expects to increase this production capacity in 2006. It also plans to start producing low osmolarity ORS. UPSM has not produced any tablets in the past. However, as part of its expansion strategy, it is interested in doing so in the future. UPSM has also expressed an interest in producing zinc. Given their lack of experience with the production of tablets, it is not clear what assistance they will need to get this production process moving.

3.2.7 Group Work Recommendations for the Action Plan

Representatives from different ministerial, NGO, and UN agencies who are part of the Zinc Technical Committee discussed the above findings and outlined the following action points that will form the principal pharmaceutical activities related to the introduction of zinc as an adjunct therapy for diarrheal treatment (see the draft action plan in section 4.0 for more details):

- Take steps to include zinc on the essential drugs list and register it;
- Estimate needs for the pilot sites;
- Determine funding modalities; and
- Identify the appropriate supply mechanism for the initial pilot districts (likely the public system for the national roll-out).

3.3 Behavior Change Communication (BCC)

Madagascar has developed innovative approaches to behavior change and community mobilization, addressing multiple causes of child mortality. These strategies have supported the delivery and use of a package of integrated services, and improved family practices. This section describes the assessment team findings that will be the basis for the introduction of zinc therapy.

3.3.1 National Level

At the national level, there is a wealth of personnel responsible for BCC, and the production of Information, Education, and Communication (IEC) materials. A Nutrition Service (*Service IEC*) with its coordinating committee (CCMS) is responsible for the coordination and validation of all IEC materials relating to health and nutrition. In addition, each technical department of the MOH has a coordinator for IEC. Furthermore, the national radio is used frequently to disseminate health and nutrition messages, and nutrition and health campaigns are often conducted (e.g., for vitamin A supplementation, polio, malaria) under the coordination of the Ministry of Health.

Most of the international agencies working in nutrition and child health have personnel or departments responsible for BCC. Care International, PSI and Santénet all consider BCC as an inherent component of their activities, and CRS and UNICEF have a department in Antananarivo responsible for communications and producing materials, such as radio spots, TV ads, and posters relating to Vitamin A supplementation, malaria, etc. PSI, is involved in various social marketing campaigns and has in-house layout specialists and graphic designers who produce state-of-the-art communications materials. The *Groupe d'Action Intégrée pour la Nutrition* (GAIN), a multisectoral body representing nutrition agents from the local and international NGOs, various ministerial departments, and the UN, is another coordination mechanism for BCC.

In addition, various materials were developed at the national level and have been disseminated to the district level, including a booklet with the IMCI algorithms with actions for children aged two months to five years, several posters on the prevention and treatment of diarrhea, the child health card, counseling cards, and gazettes that are published often with different themes relating to child health and nutrition. The gazettes were previously produced by JSI, but it could not be established who is currently responsible for producing them. There are several main messages for diarrhea prevention and treatment that are specified in the IMCI materials, as well as the counseling cards, which have corresponding pictorial images. These can be summarized as: (1) mother/ or caretaker continue to breastfeed; (2) boil water; and (3) give your child foods, particularly those they prefer. In addition, the danger signs that necessitate a health clinic consultation are described as the presence of blood in the stool, child unable to drink, has lethargy or vomiting, or has diarrhea for 3 consecutive days.

The Ministry of Health is currently recommending the use of ORS salts, as well as frequently-consumed liquids, such as coconut water, rano vola (a brownish liquid prepared by adding water to remnants of cooked rice and boiling this liquid), and rice liquid (a creamy white thick rice-water liquid produced by boiling rice in large quantities of water). The home-prepared ORS, known as *1/9* or *solution maison* is not recommended because the MOH has realized that most mothers do not prepare these in the right proportions.

3.3.2 District Level

Each district has a specialist in BCC. In addition, BCC specialists of the former provinces will now be made available to the regions. In Tulear, the Coordinator for BCC oversees BCC activities for the district and communicates with the National Ministry of Health to inform them of the districts' needs. At the time of the visit, she was involved in preparations for the polio campaign and hence the team did not get to interview her. District- and health facility- level personnel interviewed mentioned that radio spots are one of the most effective communication tools, as everybody has access to a radio. In addition, the BCC Coordinator in Tulear District cited mobile video spots as a successful method of effectuating behavior change. Currently, written materials, such as banners and posters, are produced at the central level and then transported to the districts, which are free to translate them into different dialects. In Tulear, the BCC Coordinator mentioned that her resources were limited and she could not translate these materials; rather, she preferred to be involved in the conception of these materials in the district so as to develop them in the local dialect. In Tamatave, the Director of Health of Toamasina II Region was of the opinion that written materials should not be in the local dialect, but should be in the official dialect. Most MOH staff shared this view, noting that all those who read Malagasy are able to read the official Malagasy dialect. Further information on dialect preferences and their impact on the effectiveness of BCC efforts need to be obtained with a larger sample of informants.

Health facilities at the district level were equipped with the materials (posters, counseling cards, IMCI algorithms) previously mentioned. However, it was feasible to observe only one counseling session between a health provider and a mother with a child with diarrhea (at the CSB in Andrianavory). During the visits, the teams also observed a few educational sessions. These observations reflected a wide range of competencies that may be representative of the situation in the country, but it is not possible to draw any firm conclusions in this regard. However, it is very likely that counseling skills will reflect the amount of training received and that this is an area that will need extensive support. At the district level, there is a wealth of NGOs active in child health and nutrition activities, with a strong capacity for social mobilization (such as ASOS, ADRA etc.).

3.3.3 Community Level

In a review of the IMCI program conducted in 2000, it was noted that one of the advantages of activities aiming to improve community- and family- level practices is the existence of various IEC materials exist at the community level.⁷ Field visits also found that counseling cards are available at the community level and that mothers observed at the health facilities had their children's health cards. However, we found that other materials (posters and gazette) were limited to the health centers. Community health workers expressed interest in receiving these materials, particularly the gazette.

There are a myriad of community level NGOs using innovative BCC approaches. These include MCDI, ASOS and ADRA. One of the most innovative approaches is the *Kominina Mendrika* or Champion Community approach, spearheaded by Santénet and currently in use by many of its partners, including ASOS. In this approach, communities

⁷ Ministère de la Santé. Direction de Médecine Préventive. Rapport sur la revue d'évaluation de l'introduction de la PCIME à Madagascar. 17-21 avril 2000.

set measurable, realistic and achievable objectives and indicators around specific child health themes. Then, the approach is implemented through a 10-step cycle involving introducing the theme, training community-based agents, monitoring, supervision, evaluation and awarding prizes if the theme has been adopted successfully. This approach has just been introduced to communities. Therefore, the level of its success could not be assessed. However, because *Kominina Mendrika* has strong BCC-focused elements, such as toolkits in marketing, mass media, and interpersonal communications that are made available to the communities, it is hoped that it will be successful. The assessment team members had brief discussions with Santénet about this approach, and would like to use it in the introduction of zinc for diarrheal treatment.

Another promising approach is *Reny Limy*, which means 'five mothers', and is being practiced by MCDI in Tulear. In this approach, a community member volunteers to identify five mothers who are carrying out a practice that could use improvement, then assists the mother in improving the practice (through household visits, nutrition education sessions, etc.). If the mother succeeds, the volunteer repeats this process for four other mothers, using the first mother as a witness that the new practice works. The volunteer is responsible for completing her task with a total of five mothers and is under no obligation to stay on as a volunteer. This approach has worked successfully in the promotion of family planning, vaccination, and exclusive breastfeeding.

An important factor at the community level is the engagement of local authorities, such as the presidents of the communities (*chefs des fokontany*), mayors, and other administrative leaders. Highly revered by community members, these leaders are extremely knowledgeable about health and nutrition conditions in their communities, and should be involved in planning health and nutrition programs.

Although there are successful strategies in place, structured interviews with key health staff at the national level highlighted three factors at the community level that need improvement. These factors were also noted during the field visits and include: (1) weak coordination among the different actors; (2) weak supervision of BCC activities; and (3) the absence of motivation systems for community-level agents, which may mean that activities will not be efficient and sustainable.

The assessment team noted a number of findings during the field visits that should be considered in developing a behavior change strategy for zinc. Focus groups with men at the community level in Sakarahi demonstrated a high knowledge of certain health and nutrition messages relating to optimal treatments for malaria, diarrhea, and ARI. In addition, the men were keen to receive the gazette, which was not available at the time in their village. However, there was a mixed level of knowledge about the best treatment for diarrhea by women interviewed, with some women mentioning Cotrimoxazole and Paracetamol as ideal treatments. This finding was not surprising because the health personnel in the clinic catering to this village (in the CSB in Andrianavory) provided these medicines as part of the treatment for diarrhea. Some other negative practices that were mentioned by village health workers and mothers include providing plants for treatment of diarrhea, as well as beliefs that diarrhea is due to sorcery, and that a child with diarrhea should only receive breast milk from one breast. Using plants as medication was the practice mentioned the most often during focus group discussions.

Other assessment findings should be considered in choosing communication channels in specific regions. Women turn to the authorities in the extended family structure, such as the mother-in-law and the grandmother for advice on how to look after infants and young children. Thus, any BCC approach should consider targeting these influential

people and guiding them to accept optimal practices. In one community, five out of six men, and two out of five women (Andrianavory) had a radio and used it as a major source of information. All listened to 'Radio Sakaraha' and women liked the dedication programs.

3.3.4 Group Work Recommendations for the Action Plan

Representatives from different ministerial, NGO, and UN agencies that are part of the Zinc Technical Committee discussed the above points and outlined the following action points that will form the principal BCC activities related to the introduction of zinc as an adjunct therapy for diarrheal treatment (see section 4.0 for more details on the action plan):

- Inform all the personnel at all levels on the introduction of zinc for diarrheal treatment;
- Carry out qualitative research to develop messages concerning zinc for diarrheal treatment;
- Modify existing materials and curricula, as appropriate;
- Produce new material, such as radio spots, leaflets, etc.;
- Train health workers at all levels on behavioral change for the acceptability of zinc;
- Involve all local authorities in social mobilization; and
- Organize an official launch of the introduction of zinc as part of diarrheal treatment.

3.4 Summary of Key Findings

1. There are gaps in diarrheal disease case management even among health workers trained in IMCI. This can in part be attributed to a general lack of supervision and support following training. The introduction of zinc provides an opportunity to improve the management of diarrheal diseases at the facility level by strengthening IMCI activity supervision and addressing training needs of health workers not previously trained in IMCI.
2. Through decentralization measures, the peripheral level of the health system has greater responsibility for the implementation of programs such as the introduction of zinc and new ORS. This shift in financial and programmatic decision-making from the central to the peripheral level should make funding more accessible to the districts for the introduction zinc and ORS.
3. Supervision of IMCI practices at the facility and community levels is lacking, and the introduction of zinc and ORS provides an opportunity to renew and make improvements to regular supervision.
4. Financial barriers to treatment for diarrheal diseases are significant despite insurance-type schemes and voucher initiatives to assist the poor. Further development of measures to improve financial access to services is key to ensuring that cases are appropriately treated with zinc and ORS.

5. The country's current capacity to ensure drug quality is limited, hence it is important to register zinc as a drug and import it from a reliable source with high quality standards.
6. Comparing rural and urban areas, there is a discrepancy in knowledge of and access to diarrheal disease treatment. Rural areas are at a disadvantage and should therefore be targeted for BCC interventions. Community case management will also help to close this gap by improving access to treatment in rural areas.
7. Access to zinc and ORS in urban areas can be improved through the use of the private sector (both for-profit and not-for-profit) agencies. The strategy to introduce zinc and new ORS should include private sector training and encouragement for the use of these products.
8. Madagascar is very invested in improving the national health information system. With an increase in the amount and quality of data collected, health officials and care providers need training on the use of this information.
9. The quality of drug management at the district level is variable and in most cases it is in need of improvement. Best practices should be identified and shared through training at the facility and vendor level to foster good management of zinc and ORS.

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4.0 Action Plan for the Introduction of Zinc for IMCI in Madagascar

Steps	Activities	O	N	D	J	F	M	A	M	J	J	A	S	Responsible and technical support
Delivery with or without a medical prescription	Zinc will be an OTC drug													
Drug or nutritional supplement	It is a drug classified under Table C													
Inclusion of zinc in the Essential Medicines List and Registration of Zinc	DSF send a letter requesting inclusion of zinc on the EML and a tax waiver to DPLMT	X												DSF
	DPLMT delivers a temporary authorization for inclusion on the EML and submits this to the Ministry of Finance to obtain the tax exemption.		X											DSF and DPLMT
	UNICEF, WHO, USAID and other partners provide technical support to develop the zinc registration application request and the technical specifications and application submitted to the AMM		X											SSEA
	Response on the registration request received from the AMM		X											AMM
	Revision of the list of essential drugs in 2006							X						DPLMT

4.1 Logistics

Steps	Activities	O	N	D	J	F	M	A	M	J	J	A	S	Responsible and technical support
Funding modalities	To be discussed by the Child Survival Technical Committee. The key questions are? (1) If subsidized, who will provide the subsidy? (2) Will zinc be provided free to patients? Through which mechanism?		X											Child Survival technical committee
Estimation of needs at the health facility and the community site level	Select districts with high diarrhea prevalence to serve as pilot sites Refer the decision for estimating the requirements (based on treatment dosage and duration) to the child survival technical committee with support from technical partners	X												SSEA and SSSa BASICS and RPM PLUS
Identification of supply mechanisms for use to ensure supply at community level	Refer this issue to the Child Survival Technical Committee for discussion with relevant agencies including NGOs (PSI...)		X	X										To be determined with SALAMA UNICEF

4.2 Case Management

Steps	Activities	O	N	D	J	F	M	A	M	J	J	A	S	Responsible and technical support
Selection of pilot sites	1SSD/ Region/ 3 provinces: Toamasina, Mahajanga, Toliara Questions. Compliance, respect of standards, types of health facilities (rural, urban, remote) public and private	X												SSEA and SSSA
Revision of algorithm	General revision (integration) One scenario – permanent guidelines		X											IMCI focal point
Development of training curricula	Permanent guidelines and materials		X											IMCI focal point
	Updating (quarterly reviews)			X										
	Training for health providers, community workers and drug providers			X										
Identification of staff to train	Information / sensitization/ orientation Regional and districts			X										

Steps	Activities	O	N	D	J	F	M	A	M	J	J	A	S	Responsible and technical support
	Training of service providers Heads of CSB and district hospitals Assistants of the CSB or CHD heads Drug providers			X										
Revision of data collection form (MIS)	Specific instructions to develop (message to the District Management Teams) Table 2 in the Monthly Activity Report	X												SSSa
Revision of the IMCI supervision form	Update the form (zinc)		X											
Methodology for monitoring and evaluation of pilot sites	Reports Stock management (Monthly activity report) Compliance to standards (supervision) Sentinel sites (university)		X											University with the support of BASICS

4.3 IEC/BCC/Community Mobilization

Steps	Activities	O	N	D	J	F	M	A	M	J	J	A	S	Responsible and technical support
Inform all staff at all levels	Develop tool: (protocol and rationale)		X											SSEA SIECMS-CCMS Partners Zinc technical committee
	Job aid for health workers Brochure: other targets Disseminate information after pretest		X	X	X	X								
Carry out qualitative survey	Carry out qualitative household surveys		X	X										MoH + consultants + National Statistics Institute + Zinc Technical Committee
Modify existing materials and curricula	Make an inventory of existing IEC materials and update them with the key messages			X	X									SSEA CCMS Partners (finance)
Produce new materials	Integrate zinc in the training curriculum				X	X								Zinc technical committee, SSEA, CCMS, SPC, (partners)
	Community workers Health workers													
	If needed, and based on the findings of the survey, produce new materials													

Assessment for the Introduction of Zinc in the Treatment of Diarrhea in Madagascar

Steps	Activities	O	N	D	J	F	M	A	M	J	J	A	S	Responsible and technical support
Training of health workers at all levels	Train health and community workers in BCC techniques as part of integrating zinc						X	X	X					
Involve local authorities in social mobilization	Advocacy. - Develop an advocacy kit (document + zinc sample + IEC materials) for all decision-makers (mayors, head of villages, religious leaders, regional and communal authorities)		X											All the levels of MoH and partners
	Organize the official launching of zinc introduction in diarrhea management (rationale, where to find the product)								X	X				Other sectors/ Ministries The general population Zinc technical committee Partners Others

Annex 1: List of Stakeholders Met During Assessment Team Visit

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Annex 2: Mission Activity Schedule

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Annex 3: Participants in Child Survival Technical Meeting –
Sept. 27, 2005

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Annex 4: Participants in Child Survival Technical Meeting –
October 6, 2005

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Annex 5: Scope of Work

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Annex 6: Estimated Requirements for Zinc by District

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Annex 7: Country Assessment Tool for the Introduction of Zinc in the Clinical Management of Diarrhea

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